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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/589,905

12/05/2006

Shinya Yamanaka

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02/17/2010

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EXAMINER

CROUCH, DEBORAH

ART UNIT

PAPER NUMBER

1632

NOTIFICATION DATE

DELIVERY MODE

02/17/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/589,905	Applicant(s) YAMANAKA, SHINYA	
	Examiner Deborah Crouch	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on June 16, 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 22-25 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 22-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on August 18, 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/20/09</u> . | 6) <input type="checkbox"/> Other: _____ |

Applicant's arguments filed June 16, 2009 have been fully considered but they are not persuasive. The amendment has been entered. Claims 1-16 and 22-25 are pending.

The rejection of claims 2, 6, 7, 10 and 11 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement made in the office action mailed March 24, 2009 is withdrawn.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 and 22-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for screening methods for a somatic cell nuclear reprogramming substance that affects expression of ECAT3, ECAT4 and ECAT5, does not reasonably provide enablement for methods of screening for factors that affect expression of ECATs in general or specifically ECAT1, ECAT2, ECAT6, ECAT7, ECAT8 and ECAT9. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 7, 10, 11 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in

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the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 7, 10, 11 and 12 are drawn to screening methods for a somatic cell reprogramming substance that affects expression of ECAT1, ECAT2, ECAT6, ECAT7, ECAT8 and ECAT9, or combination of these ECAT genes.

The claims are not enabled because a role for ECAT1, ECAT2, ECAT6, ECAT7, ECAT8 and ECAT9 in maintaining pluripotency and self-renewal has not been established. While it is acknowledged in the specification that these ECAT genes are expressed in mouse and human ES cells, there is no correlation that these ECAT genes would function to reprogram a somatic cell. By "reprogramming a somatic cell", it is meant that the somatic cell is returned to a less differentiated state that has pluripotency and self-renewal similar to an ES cells (specification, page 21, line 33 to page 22, line 6). While Fbx15 (ECAT3), Nanog (ECAT4) and Eras (ECAT5) are known to function in maintaining pluripotency or self-renewal, the role of ECATs 1, 2 and 6-9 are not known (specification, page 2, line 17 to page 3, line 8). Thus, the skilled artisan would not know how to use any factors found to stimulate expression of these ECAT genes. The skilled artisan would not know if the factors would induce a less differentiated state on the somatic cell. There is no evidence of record or in the art that the specific genes expressed in embryonic cells are "reprogramming factors" as defined by the specification. Based on this, the skilled artisan would have needed to engage in an undue amount of experimentation without a predictable degree of success to make and use the invention as claimed at the time of filing.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 15, there is confusion as to supplying ECAT4 to a cell and bringing the cell in contact with a test substance. The claim is not clear as to how one would discern an effect of supply ECAT4 from the effect of the test substance.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 3, 4, 6, 13, 14, 22, 24 and 25 are rejected under 35 U.S.C. 102(f) as being clearly anticipated by PgPub 20080280362. efd. November 26, 2003 (Jaenisch).

Jaenisch teaching an in vitro assay for determining compounds that affect expression of pluripotency genes, such as Oct-4, Nanog (ECAT4) and Stella, where a transgenic cell comprising a selectable marker gene, such as an antibiotic resistance gene, operably linked to a pluripotency gene promoter is treated with an agent ([0027],

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[0035], [0058] and [0059]). Cells that express the marker gene are then selected as reprogrammed cells, thereby identifying or selecting the agent as a "reprogramming agent ([0058]). For example, when the marker gene is for antibiotic resistance, those cells that survive the antibiotic are deemed selected ([0029]). Jaenisch teaches the transgenic cell can be isolated from a heterozygous transgenic mouse whose genome comprises a single selectable marker knocked-in to a pluripotency gene such that the marker gene is regulated by the pluripotency gene promoter ([0033]). Thus, Jaenisch clearly anticipates the claimed invention.

Claims 5, 7-12, 15, 16 and 23 are free of the prior art. At the time of filing, the prior did not teach or suggest methods of screening for a somatic cell nuclear reprogramming substance in accordance to the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is (571)272-0727. The examiner can normally be reached on M-Fri, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah Crouch/
Primary Examiner, Art Unit 1632